REMARKS

The pending Action rejects the product claims 1-5, 7, and 9-28 under 35 USC 103(a) as unpatentable over Applicant's European Patent EP 0 217 821 B, in view of Applicant's 1991 SPIE Article, termed by the Examiner "Begleiter II." (The Action states that claims 1-28 remain pending, but claims 5 and 8 were cancelled in the Amendment filed September 22, 2005.)

The foregoing Amendment in claim 11 deletes "an aqueous solution of" as possibly confusing given that the claimed holographic layer on a dosage form is a solid layer that is thermally reversible to form the solid diffraction relief therein.

Claim 18 adds "or formed with," to make it clear that the pharmaceutically active ingredient is within the holographic layer, without limitation in the way the incorporation occurs. Support for the amendment appears in the specification at page 25, lines 1 to 8.

Applicant respectfully traverses the Section 103 rejections.

The European '821 patent corresponds generally to Applicant's U.S. Patent No. 4,668,523 which is cited and distinguished in the above-identified application at pages 1 to 4. The '523 patent was also cited by Examiner DiNola-Baron in the first Office Action herein on the merits, and overcome by the Response filed on August 10, 2004.

The 1991 Begleiter II SPIE Article is cited on page 2 of the instant patent application, and also distinguished on pages 2-4. The citation of HPMC as a material used in a holographic element appears in the European '821 patent and in the Begleiter II SPIE Article.

Applicant does not claim as the present invention any one material, such as HPMC, or edible products generally. What Applicant does claim is a pharmaceutical dosage form with a certain structure, formed of certain constituent materials, and having certain characteristics, that create durable holographic images and effects.

"Pharmaceutical dosage form" is an affirmative structural limitation of the pending claims.

The prior art of record discloses only one pharmaceutical dosage form, a tablet of powder that is cold-compressed in a die with a holographic pattern that it presses into the tablet. This tablet is described in Part 4 of the SPIE Article, page 104, and mentioned there for possible use as a children's vitamin. All of the other holographic products disclosed in the cited prior art are food products (including candies), not pharmaceutical dosage forms. The purpose of the holographic effects on the food products are described as decorative and aesthetic.

To produce a holographic food product, the cited prior art teaches that the holographic element is formed from a liquid solution that is poured into a flat mold (with a holographic pattern formed on its upward directed face), dehydrated over a substantial period of time to form a film with the holographic pattern on one face, and demolded. The resulting cast or "deposited" film is cut, or otherwise formed, into smaller size elements, and the cut elements are applied to the food product. The EP '821 patent also discusses the holographic element itself being the confection.. The only exception in the prior art to such cast or deposited film as the holographic element are 1) the disclosure of the experimental cold-compressed tablet and 2) the discussion of experimental "Holographic Replication in Hard Sugar Confectionery," part 6 of the SPIE Article at page 105. Heat stamping of a hard sugar confection to form a relief grating (holographic pattern) is mentioned.

Applicant submits with this Response his Declaration Under Rule 132. This Declaration provides a discussion of Applicant's work leading to the European '821 and Begleiter II references, and then Applicant's work leading to the present invention. This Declaration reinforces the fundamental differences noted in the present application itself between a holographic pharmaceutical dosage form and the holographic food products described in the cited prior art. This Declaration also establishes that: 1) holographic food products carrying dehydration cast holographic element were the only workable prior art holographic food products known to Applicant (and they continue to be used in

commercial manufacture even now); 2) a thermoformable holographic layer is used for pharmaceutical dosage forms and this structure and a material with this characteristic is significant to creating a workable holographic pharmaceutical dosage form; and 3) the holographic food products made according to the teachings of Applicant's EP '821 patent or his SPIE Article had short product lives, of "9 months or less." The prior art products were not "stable," as now claimed. Moreover, the Declaration clarifies and establishes that the tablets and heat-stamped hard confectionery products disclosed in Part 6 of Applicant's SPIE Article were not stable enough for use as the claimed holographic pharmaceutical dosage forms.

As also detailed in the Declaration, despite the long-felt, multi-billion dollar needs in the pharmaceutical industry for the advantages of the present invention in non-chemical coloration, brand differentiation, and anti-counterfeiting of dosage forms, and even with the benefit of the actual knowledge of the cited prior art, it required man-years of experimentation by Applicant and others working under his supervision to make the invention now claimed.

In particular, the Begleiter Rule 132 Declaration provides specific reasons why it would not be "obvious," to use either the EP '821 patent disclosure or the SPIE Article (Begleiter II), or to combine them, to reach the present claimed invention. One overriding reason is that none of the prior art solutions as actually implemented, including those using HPMC, HPMC with plasticizers, or any compressed powder tablet or vitamin, produced a holographic relief that was stable, as described and claimed in the present application. The SPIE Article itself is clear at page 105 that an acceptable life of a holographic relief for food products was only "9 months or less." The non-dehydrated/cast products -- the compressed powder tablet and the "Part 6" hard sugar confectionery, had an even shorter life expectancy. (Declaration, ¶ 9, 11). They were not stable, as claimed. Nor did they have a layer with a holographic relief overlying a core, as required by claims 2-5, 7, 9-17, and 19-28.

The 132 Declaration at paragraphs 8 and 14 details some of the reasons for this lack of stability in the prior art products. But regardless of the reasons, what is

clear is that the prior art did not teach one how to produce a stable holographic relief for a pharmaceutical dosage form. Indeed, the cited references teach away. As a whole, the SPIE article (Begleiter II) teaches that one should use the cast, dehydrated element for food products, and cold-compression of the constituent materials, with no layer of a relief carrying material over a core, to produce a pharmaceutical dosage form, a tablet or children's vitamin. Heat required in thermoforming is contra-indicated for pharmaceuticals where active ingredients are typically degraded by heat.

To re-cap, the Begleiter candy patent, EP '821, does disclose HPMC and plasticizers, but it teaches a food/candy product, one that is not stable (as presently claimed in light of the specification), and one that does not use a thermoformable layer. It teaches no holographic pharmaceutical dosage form, including the many specific problems encountered in the present specification, prior Remarks herein, and the accompanying Rule 132 Declaration. It does not direct one how to modify its disclosure to produce a pharmaceutical dosage form. It teaches nothing about thermoformability of any materials, or how to achieve the stability of the holographic relief on a pharmaceutical dosage form end product.

The SPIE Article teaches away from the present claimed invention, and provides no motivation or suggestion to combine the teachings of the EP '821 patent with the SPIE Article to result in the claimed holographic pharmaceutical dosage form. The SPIE Article teaches a cold compressed powder dosage form. There is no motivation to, somehow, combine the materials and casting processes of the food products, including cast HPMC, with cold compression. One would combine the EP '821 patent and the SPIE Article to see the present claimed invention only with the hindsight of the present invention.

The 132 Declaration also addresses certain *Graham v. Deere* secondary factors -- long felt need and problems, failure of the prior art to solve these problems and meet these needs, and the success of this invention in securing the support of a major pharmaceutical company having a license to it. There was clearly a long-felt need in the pharmaceutical industry for a way to create colors and visual effects without

the use of chemical requiring additional administrative approval, achieve better brand differentiation, and better resist counterfeiting. Going from his own prior art to the present invention took Applicant man-years of diligent effort and failed experiments. The results achieved a license from a major pharmaceutical company for rights in the present invention. The developments of Applicant have been noted and followed by Johnson & Johnson (albeit using a holographic relief internal to the product as taught in Applicant's co-pending U.S. patent application Serial No. 10/483,312 filed January 8, 2004.) It is also instructive that Merck GmbH has turned to mica as a coating additive to provide some of the benefits of the present invention, but without the advantages of holograms, and with the burden of governmental "FDA"-type approval worldwide.

No prior art teaches or suggests that a holographic effect produced by a diffraction relief in a layer of a pharmaceutical dosage form can respond controllably to temperature and humidity so that, as stated in claim 3, "a visible change in said holographic image or effect is an indication of exposure to excessive heat and/or humidity." (Claims 3, 5, and 19-24).

Heat fusion of the outer layer to an underlying core, avoiding the use of an adhesive layer, is likewise significant, not found in the art of record, and patentable. Claims 15 and 16 are directed to this feature.

Forming the outer holographic layer as the capsule that holds a pharmaceutically active ingredient is also novel and significant. This feature is defined by claim 17.

The strip form of the invention shown in Fig. 10 and defined by claims 1 and 18 is novel and patentable. Applicant is aware of no prior art that placed a pharmaceutically active ingredient into a layer of a thermoformable material that forms a stable diffraction relief.

The use of waxes in a holographic relief layer is also novel, both to influence the amount of heat used in and the duration of the forming, or the diffraction relief, and

in controlling the temperature response of the relief. Claims 11, 12/11, 13/12, 16, 20 and 21 claim wax as a constituent material of the layer.

The features defined in claims 25-28 relating to controlling twinning during pan coating are also novel and patentable. The prior art of record does not even recognize the twinning problem, let along propose a solution to this problem. Tablets are the leading form of pharmaceutical dosage form. A solution to the problem of twinning as an outer layer is applied to tablet cores is significant. Flat holographic relief patterns are optically desirable to create images and effects, but flat outer surfaces on dosage forms promotes twinning. Note that while Applicant's SPIE Article mentions tablets, they are formed by cold-compressing a powder. The SPIE Article teaches no outer tablet layer, and no pan coating of such an outer layer onto a tablet core.

Applicant also submits herewith a further Supplemental Information Disclosure Statement, together with the requisite fee under 37 CFR 1.97(c).

For the foregoing reasons, and for the reasons detailed in the accompanying Rule 132 Declaration, Applicant respectfully argues that the pending claims define novel and patentable subject matter over the art of record. This application is deemed in condition for allowance, which is respectfully requested.

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Respectfully submitted,

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